EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2020
EMA/CHMP/343884/2020
Media and Public Relations

Press release

New treatment to enable kidney transplant in highly sensitised patients

EMA has recommended granting a conditional marketing authorisation in the European Union for Idefirix (imlifidase), the first treatment for adult patients waiting for a kidney transplant, who are highly sensitised against tissue from the donor and who have a positive crossmatch test against an available kidney from a deceased donor. Idefirix should be used complementary to existing allocation programmes for patients with a very low chance of finding a matching kidney despite such programmes.

When a kidney from a deceased donor is offered for transplant, crossmatch tests are performed against all patients on the waiting list. The test checks whether a patient has specific antibodies against the potential donor.

Highly sensitised patients have exceptionally high antibody levels that react to the donor's tissue which shows up as a positive crossmatch test, making it more likely that the body will reject the donor organ. Patients with this result are therefore not eligible for transplant, and the available kidney is typically offered to other patients on the waiting list. There is an unmet medical need to desensitise these patients and convert a positive crossmatch into negative for them to become eligible for kidney transplantation.

Idefirix is made of an enzyme derived from the bacterium *Streptococcus pyogenes*, which breaks down antibodies called Immunoglobulins G (IgG). IgG is produced by the patient against the transplanted organ. By breaking down IgG, the medicine is expected to prevent the patient's immune system from attacking the newly transplanted organ, thereby reducing the risk that the organ will be rejected.

Idefirix was supported through EMA's PRIority MEdicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support to medicines that have the potential to address patients' unmet medical needs. Idefirix was granted eligibility to PRIME on 18 May 2017 for prevention of graft rejection following solid organ transplantation.

Idefirix is recommended for a conditional approval, one of the EU's regulatory mechanisms to facilitate early access to medicines that fulfil an unmet medical need. This type of approval allows the Agency to recommend a medicine for marketing authorisation with less complete data than normally expected, in cases where the benefit of a medicine's immediate availability to patients outweighs the risk inherent in the fact that not all the data are yet available. The company must now submit

additional efficacy and safety data based on one observational follow-up study and one post-approval efficacy study.

The efficacy and safety of Idefirix as a pre-transplant treatment to reduce donor specific IgG and enable highly sensitised transplant candidates to be eligible for kidney transplantation, was studied in three open label, single arm, six-month clinical trials. In these studies, 46 sensitised patients were transplanted. All patients who were crossmatch positive when included in the study were converted to negative within 24 hours after treatment with imlifidase. The studies showed also excellent results on kidney function and graft survival after six months. The most common adverse reactions reported with this treatment were infections, such as pneumonia, urinary tract infection and sepsis and infusion-related reactions. The effect of Idefirix is temporary, and therefore does not preclude the need for standard immune suppression in kidney transplant patients.

The opinion adopted by the CHMP is an intermediary step on Idefirix's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Idefirix is Hansa Biopharma AB from Sweden.
3. Idefirix was designated as an orphan medicinal product on 12 January 2017 in the following indication: Prevention of graft rejection following solid organ transplantation.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News